

REMARKS

The above-identified application has been reviewed in light of the Office Action mailed on August 24, 2010. By the present amendment, the Applicants have amended claims 1, 19, and 28. Additionally, the Applicants have added new claim 31. It is respectfully submitted that the pending claims are fully supported by the specification, introduce no new matter, and are allowable over the references of record.

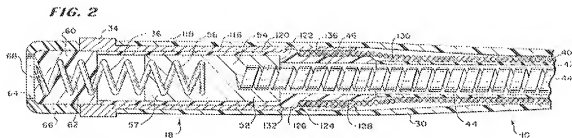
The Applicants would like to thank Examiner Yabut for the courtesies extended to the Applicants' representative, Dana A. Brussel, during a telephone interview held on November 5, 2010. During the interview, the Applicants' representative and Examiner Yabut discussed proposed amendments to independent claims 1, 19, and 28 in view of the cited references. The Applicants have incorporated Examiner Yabut's helpful suggestions into the present amendment.

In the Office Action, claims 1-30 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. According to the Office Action, an inconsistency existed between the language of the preamble and the body of the claim. In response thereto, the Applicants have amended the preamble of claims 1, 19, and 28 to clarify the scope of the claims. It is respectfully requested that the rejection of claims 1-30 under 35 U.S.C. § 112, second paragraph be withdrawn.

In the Office Action, claims 1, 4-6, and 19-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,628,943 to Miller ("Miller"). According to the Office Action, Miller discloses all the features recited in claims 1, 4-6, and 19-30, but fails to disclose a plurality of fasteners. The Office Action stated that it would have been obvious to provide a plurality of fasteners with the device disclosed in Miller. The Applicants respectfully disagree and traverse the rejection for the reasons detailed below.

As amended, claim 1 recites an applicator including, *inter alia*, an outer tube, an actuator, a plurality of electrically non-conductive fasteners, and a rotator having a longitudinal groove configured to receive a portion of at least two fasteners of the plurality of fasteners, wherein actuation of the rotator ejects at least one fastener of the plurality of fasteners from the terminal end.

In contrast to the applicator recited in independent claim 1, Miller relates to an implantable pacing lead having a single, electrically conductive cardiac electrode that is insertable into heart tissue. Briefly, as illustrated below in Figure 2 of the Miller reference, a distal end 46 of a helical drive member 44 is mechanically connected to a proximal end 52 of a cylindrical mounting member 54 that is rotatably mounted within an electrode assembly 18. A proximal end 56 of an electrically conductive securing device 36 is mounted to a distal end 57 of the cylindrical mounting member 54. A plug 60 is disposed at a distal end of the electrode assembly 18. The plug 60 includes a spiral passageway 62 for receiving the securing device 36 therein. A space is defined between the distal end of the mounting member 54 and the proximal end of the plug 60.



As configured, rotation of the helical drive member 44 causes rotation of the mounting member 54 and the securing device 36. Thus, "the securing device 36 is rotated through the passageway 62 in a screw like manner and exits the passageway 62 through an opening 64 in an

insulative tip member 66.” (Miller at Col. 6, ll. 15-18). Since the proximal end 56 of the securing device 36 is mounted to the distal end 57 of the mounting member 54, as the securing member 36 moves forward through the passageway 62 in a screw like manner, the forward movement of the securing device 36 acts to longitudinally/axially reposition the mounting member 54 distally through the space until it contacts the proximal end of the plug 60.

Miller’s pacing lead 10 only includes a single securing device 36 and does not eject the securing device 36 from the distal electrode assembly 18. Rather, Miller’s device is specifically configured such that the securing device 36 is retained within the distal electrode assembly 18 for forming the anode portion of the electrical circuit. As disclosed in Miller, the electrical circuit (i.e. conductive path) is formed when the securing device 36 is inserted into an atrium or ventricle of a heart after the lead 10 is implanted, which establishes the anode connection. Then a cathode connection is established from terminal pin 22 to ring electrode 34 with the anode connection being from anode ring 24 to securing device 36. (see Miller at Col. 7, ll. 62-68). Separating the securing device 36 from the pacing lead 10 would sever the electrical connection, thereby defeating Miller’s intended purpose. Miller’s device is specifically designed and constructed for use with a single electrically conductive securing device and is not suitable for accommodating a plurality of electrodes. There is no disclosure or suggestion in Miller for a plurality of electrodes. Further still, Miller fails to disclose or suggest an electrically non-conductive fastener as recited in amended independent claim 1.

Thus, Miller fails to anticipate or suggest the device recited in amended independent claim 1. Therefore, it is respectfully submitted independent claim 1 is in condition for allowance. Since claims 4-6 and 23-25 depend from independent claim 1, it is respectfully submitted that these claims are also in condition for allowance.

As amended, independent claim 19 recites an applicator having, *inter alia*, an outer tube, an actuator, a rotator having a longitudinal groove, and a plurality of fasteners disposed about the rotator, each fastener having a portion thereof positioned within the longitudinal groove of the rotator, wherein actuation of the actuator results in rotation and translation of each fastener of the plurality of fasteners relative to the outer tube and the rotator remains axially stationary with respect to the outer tube. Similarly, independent claim 28, as amended, recites an applicator including, *inter alia*, a plurality of fasteners and a rotator having a longitudinal groove that engages a portion of each fastener of the plurality of fasteners.

As discussed hereinabove, Miller's device is specifically directed towards a single securing device disposed in the electrical assembly. Miller fails to disclose or suggest that the electrical assembly is capable of housing a plurality of securing devices. Miller's device is specifically designed and constructed for use with a single securing device and is not capable of accommodating a plurality of electrodes or securing devices. There is no disclosure or suggestion in Miller for a plurality of electrodes or securing devices.

Further still, Miller's disclosure is directed away from the claimed subject matter since operation of Miller's device necessitates rotation and longitudinal translation of the mounting member 54, while maintaining a connection between the securing device 36 and the pacing lead 10. Miller's disclosed pacing lead 10 is not capable of rotating more than one securing device 36 since the proximal portion of the securing device 36 remains connected to plug 60 of the pacing lead 10.

Thus, Miller fails to anticipate or suggest the applicator recited in independent claims 19 and 28. Therefore, it is respectfully submitted that independent claims 19 and 28 are in condition for allowance. Since claims 20-22, 26, and 27 depend from independent claim 19 and claims 29

and 30 depend from independent claim 28, it is respectfully submitted that these claims are also in condition for allowance.

In the Office Action, claims 2 and 3 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Miller in view of U.S. Patent No. 4,596,350 to Smith et al. ("Smith"). The Office Action alleged that Miller discloses the claimed device except for the lock/clip indicator and relied upon Smith to supply the features missing from Miller. Adding the lock/clip indicator and load spring of Smith to Miller fails to cure the deficiencies of Miller. Smith fails to disclose or suggest any additional features that, in combination with Miller, suggest, as a whole, the applicator recited in claims 2 and 3. Since claims 2 and 3 depend from independent claim 1, it is respectfully submitted that these claims are in condition for allowance for at least the same reasons independent claim 1 is allowable.

Claims 7 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Miller in view of U.S. Patent No. 5,100,420 to Green et al. ("Green"). According to the Office Action, Miller discloses all the claimed features except that the distal portion and the proximal portion are releasably secured together with the distal portion being disposable and the proximal portion being reusable. Adding the distal and proximal portions of Green fails to cure the deficiencies of Miller. Green fails to disclose or suggest any additional features that, in combination with Miller, suggest, as a whole, the applicator recited in claims 7 and 8. Since claims 7 and 8 depend from independent claim 1, it is respectfully submitted that these claims are in condition for allowance for at least the same reasons independent claim 1 is allowable.

Claims 9-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Miller in view of U.S. Patent No. 5,607,436 to Pratt et al. ("Pratt"). The Office Action asserted that Miller discloses all the claimed features except for a lever, a lead screw, and a nut driver. The Office

Action relied upon Smith to disclose the features absent in Miller. Adding the lever of Pratt fails to cure the deficiencies of Miller. Pratt fails to disclose or suggest any additional features that, in combination with Miller, suggest, as a whole, the applicator recited in claims 9-16. Since claims 9-16 depend from independent claim 1, it is respectfully submitted that these claims are in condition for allowance for at least the same reasons independent claim 1 is allowable.

The Office Action rejected claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Miller in view of Pratt and further in view of U.S. Patent No. 5,487,500 to Knodel et al. ("Knodel"). The Office Action alleged that Miller and Pratt disclose the claimed device, but fail to disclose a plurality of teeth and relied upon Knodel to supply the missing disclosure. Adding the mid-section extension of Knodel fails to cure the deficiencies of Miller and Pratt. Knodel fails to disclose or suggest any additional features that, in combination with Miller and Pratt, suggest, as a whole, the applicators recited in claims 17 and 18. Since claims 17 and 18 depend from independent claim 1, it is respectfully submitted that these claims are in condition for allowance for at least the same reasons independent claim 1 is allowable.

As part of the Applicants continuing duty of disclosure, the Applicants are informing the Examiner that U.S. Patent Application Serial Number 11/978,893, a related family application is presently docketed to Examiner Yabut in art unit 3734. In an Office Action mailed on October 25, 2010, claims 12-17 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,212,865 to Davis et al.

By the present amendment, the Applicants have added new claim 31. As discussed hereinabove, independent claim 28 is neither anticipated nor suggested by the references of record. Since new claim 31 depends from independent claim 28, it is respectfully submitted that new claim 31 is in condition for allowance.


Appl. No. 10/755,427
Amendment dated November 24, 2010
Reply to Office Action Mailed August 24, 2010

In view of the foregoing, reconsideration of the application and allowance of claims 1-30 is earnestly solicited. Should the Examiner desire a telephonic interview to resolve any outstanding matters, the Examiner is sincerely invited to contact the undersigned at (631) 501-5713.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

Respectfully submitted,

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